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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | E | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---|---------------------|
| 08/491,892 | 07/14/795 | HANSEN | | |

12M2/0213

EXAMINER
BARDOLI, ECUSHMAN DARBY AND CUSHMAN
1100 NEW YORK AVENUE NW
NINTH FLOOR
WASHINGTON DC 20005-3918ART UNIT
1200PAPER NUMBER
02/13/97DATE MAILED:
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | |
|------------------------------|--------------------------------------|--------------------------------------|
| Office Action Summary | Application No. 08/491,892 | Applicant(s) Hansen et al. |
| | Examiner Barbara Radio | Group Art Unit 1209 |

Responsive to communication(s) filed on Jan 9, 1997

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-8 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-8 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit:

Final Office Action on the Merits

Status of the Application

1. The amendment filed January 9, 1997 has been entered by the examiner.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claims 1-5 under 35 USC § 103 over Calverley et al. ('048) in view of Jolly et al. ('325) is maintained and claims 6-8 are rejected 35 USC § 103 over Calverley et al. ('048) in view of Jolly et al. ('325).

Applicant argues that Jolly et al. do not teach that the hydrated form of $1\alpha,25$ -dihydroxycholecalciferol is more stable than the anhydrous form of the same compound. The argument is not persuasive for the following reason.

Jolly et al. teach $1\alpha,25$ -dihydroxycholecalciferol is difficult to crystallize and, thus, is not suitable for

Art Unit:

pharmaceutical use (col. 1, lines 5-27). The reference also teaches the monohydrate of the $1\alpha,25$ -dihydroxycholecalciferol is very stable, perfectly crystalline and easily obtained in the pure form (col. 1, lines 47-53). One having ordinary skill in the art would know from the reference that hydrated form of $1\alpha,25$ -dihydroxycholecalciferol is more stable than the anhydrous form of the same compound.

Claims 7-8 recite a method of preparation of the compound and its use in the preparation of a gel formulation. However, Jolly et al. teach a process for the preparation of the monohydrate of $1\alpha,25$ -dihydroxycholecalciferol comprising dissolving the compound in an organic solvent and the addition of water to the solution to form the hydrated compound (col. 1, lines 58-64). The reference teaches the use of the monohydrate in pharmaceutical compositions (col. 2, lines 4-16). Therefore, it would have been obvious to one having ordinary skill in the art to make the monohydrate of calcipotriol using the process as taught by Jolly et al. with reasonable expectation that the monohydrate would have the advantages taught by the reference.

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Claim 8 differs from the reference by reciting the storage stability of the compound at 40°C. The reference is silent about the temperature at which the monohydrate is stable and, thus, includes all temperatures including 40°C. The determination of the temperature at which the compound is stable is well within the level of skill of one skilled in the art.

For these reasons and those given in Paper No. 4, the rejection of claims 1-5 under 35 USC § 103 Calverley et al. ('048) in view of Jolly et al. ('325) is maintained and claims 6-8 are rejected 35 USC § 103 over Calverley et al. ('048) in view of Jolly et al. ('325).

Telephone Inquiry Contacts

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Radio whose telephone number is (703) 308-4595. The examiner can normally be reached between 7:30 am and 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.



JOSE G. DEES
SUPERVISORY PATENT EXAMINER
GROUP 1200

BB

February 4, 1997